Contraception

Effectiveness of Diaphragm and Jelly in a Well-Motivated Group of Clinic Patients

HENRY J. OLSON, *M.D.*, LUCILLE WOLF, *R.N.*, DOROTHEA BEHNE, *M.D.*, JERRY UNGERLEIDER, *M.D.*, and EDWARD T. TYLER, *M.D.*, Los Angeles

• With the increasing availability of new forms of contraception it is of importance to relate data obtained with new techniques to that obtained with diaphragm and jelly. This report provides statistical information relative to incidence of pregnancy in a relatively carefully-controlled group of clinic patients. Eighteen pregnancies occurred among 659 patients who used the method for a total of 7,353 cycles.

FOR SEVERAL YEARS the Los Angeles Planned Parenthood Clinic has been studying a variety of new, experimental methods of conception control. During this period many of the patients, for a variety of reasons, have employed the so-called "standard" contraceptive method—diaphragm and jelly. However, we have not previously reported any data relative to this method. Therefore, when we were asked about two years ago to evaluate the use of diaphragm with a new jelly,* we proceeded with a controlled study of this method in the hope that it would provide comparative data relative to newer methods.

The actual clinical effectiveness of any contraceptive technique in a Planned Parenthood Center is dependent, of course, upon many factors, including the kind of clinic, the personnel and, of more importance, the patients' motivations and the particular method used. Since the way the clinic operates is a factor, a brief discussion of the routine of the Los Angeles center is in order.

It is the custom of the Los Angeles Planned Parenthood Center to provide patients with a choice of several contraceptive methods, provided there is no contraindication to a specific method. For example, patients are given choices of diaphragm and jelly, gel or cream alone, suppositories and various other miscellaneous local methods and the much-publicized oral method. Each of the methods available is described in detail during a group lecture given by a senior nurse to all new patients at each clinic session. During the lecture the advantages and disadvantages of each method are described and patients' questions are welcomed. When the patient decides on a specific method, one of the nurses gives her individual instruction in the use of it. A large proportion of women attending the Los Angeles Center are postpartum patients who have elsewhere requested referral for contraception. Therefore, one might infer that, in general, the patients herein discussed are well motivated both as to a wish for contraception and as to method. This is important to emphasize since motivation in this series may be considered far greater than in studies where "missionary" work of some kind is being attempted. In the latter instances, efforts are made to encourage contraception by people—for example, in overpopulated areas—who may not be particularly interested in it.

We are also fortunate in having a staff of persons who are very efficient in instructing patients in the use of various methods, stressing the need for continuous use and achieving a good degree of rapport with patients. This, of course, also leads to a better degree of effectiveness, regardless of the method.

With the current availability of several of the newer methods, there has been decreasing demand for the diaphragm and jelly method. This has resulted from word-of-mouth information passed along from patient to patient. Seven or eight years ago, perhaps 90 per cent of clinic patients used the diaphragm and jelly method, now no more than about 20 per cent use it; and those who are still using it are persons who, having done so successfully for some time, are reluctant to change, patients who were specifically referred to the clinic for diaphragm and jelly by physicians or postpartum centers, or patients who have long felt that diaphragm and jelly is the standard method or have been led to believe this.

During the period from October 1, 1957, to July 31, 1959, a total of 659 women were given and used

*Lanesta Gel, supplied through the courtesy of the George Breon Company.

Submitted September 21, 1960.

TABLE 1.—General Data Concerning 659 Patients in Group of Users of Diaphragm and Jelly Method of Contraception

1. *Age Groups (Years):*	
14 to 19	154
20 to 24	281
25 to 29	249
30 to 34	207
35 to 39	98
40 to 44	16
45 and over	8
2. *Nationalities:*	
Negro	605
White	284
Mexican	114
Others	10
3. *Education:*	
Elementary (grades 1 to 6)	369
Junior High (grades 7 to 9)	297
Senior High (grades 10 to 12)	281
College	46
Education (continued):	
Unschooled (no formal education)	20
4. *Previous Marriages:*	
Husbands	42
Wives	61
5. *Years Married:*	
1 to 5	446
6 to 10	311
11 to 15	168
16 to 20	71
25 to 30	3
6. *Occupation:*	
Housewives	765
Skilled trades	73
Unskilled trades	49
Professional	107
Students	19
7. *Coital Frequency:*	
Less than once a week	169
Once to twice a week	351
Three to six a week	430
Seven and over a week	63
8. *Previous Methods of Contraception Control:*	
No protection	138
Withdrawal	167
Diaphragm	101
Safe period	55
Cr, gels, jelly alone	81
Douching only	187
Films	18
Others	27
Condoms	181
Suppositories	46
Oral	8
Buttons	4

TABLE 2.—Reproductive Data Concerning 659 Patients in Group of Active Uses

9. *Previous Pregnancies:*	
None	162
One	161
Two	301
Three	111
Four	74
Five	66
Six	38
Seven	28
Eight	30
Nine	16
Ten and over	26
10. *Incomplete Pregnancies:*	
Abortions	739
Stillbirths	31
Ectopic pregnancies	9
Premature (nonsurvive)	27
11. *Number Living Children per Family:*	
None	52
One	199
Two	126
Three	98
Four	161
Five	83
Six	76
Seven	82
Eight	65
Nine	40
Ten and over	46

diaphragms and the specific gel employed in this study.*

Warner evaluated this new contraceptive gel in humans, particularly with reference to vaginal tolerance.[4] After prescribing the gel for 149 women who inserted it into the vagina on 21 consecutive days, Warner concluded: "The gel was well tolerated by the genital mucosa, subjectively and objectively, and there were no significant hematological alterations demonstrated by blood counts performed before initiation and upon completion of this study."

Warner further stated: "A total study of 162 women who used the gel over varying periods of time to 12 months indicates that this gel is well tolerated when used for extended periods of time and well accepted by patients."

Berberian, Coulston and Slighter[2] also investigated the toxicity of the gel in laboratory animals. They stated: "The gel was not irritating when topically applied to the abraded skin of rabbits. It produced no vaginal irritation or alteration in mucosal architecture or secretions when introduced into the vagina of monkeys three times weekly for 41 weeks." Further, these investigators noted that 11 men applied the gel liberally to penile surfaces for eight hours or longer and no irritation of any kind was observed.

The maximum period of use for which data are available in the present study was 22 months. Twenty-nine of the 659 patients in the group studied used it that long. The data on others were for lesser periods (Table 1). General information regarding the 659 subjects is given in Table 1, and reproductive data in Table 2.

Patients receiving this method were given the usual instruction on applying the jelly and diaphragm which is considered routine for this method. They were told to make sure the diaphragm and jelly were applied exactly according to instructions. Clinic nurses teach the method in the following manner:

Following bimanual examination by a physician, the patient is requested to lean on her left elbow and examine herself so that she may become familiar with the location of the cervix and the pubic arch. When fully taught, she recognized the lower edge of the pubic bone and the anterior

*The formula is as follows: Sodium chloride, 10.0%, ricinoleic acid, 1.0%; chlorindanol (7-chloro-4-indanol), 0.1%; sodium lauryl sulfate (Duponol PC), 0.2%; glycerin, U.S.P., 10.0%; tragacanth, 2.5%; methyl-p-hydroxybenzoate, 0.1%; calcium hydroxide, U.S.P., 0.027%; perfume, 0.006%; lactic acid to pH 4.8-5.0.

TABLE 3.—*Pregnancies Occurring During Use of Method by 659 Patients (Pregnancies—18)*

1. Pregnant on admission	5
2. Planned pregnancies	4
2 patients used method 6 each month and each became pregnant first month when discontinued.	
1 patient used 9 months and became pregnant second month when discontinued.	
1 patient used 13 months and became pregnant fourth month when discontinued.	
3. Planning a pregnancy and as of survey date had not conceived	2
1 patient used 9 months and had been trying three months.	
1 patient used 5 months, been trying 5 months and had not conceived yet.	
4. Unplanned pregnancies	7
1 patient used 14 months "then started to practice withdrawal in her not fertile period" became pregnant second month.	
1 patient used 8 months, ran out of supplies, so used douching and became pregnant first month.	
2 patients used for 4 months each, ran out of supplies; 1 used condom, pregnant first month; and other tried douching and pregnant second month.	
2 patients used 3 months each—1 used vaseline, pregnant first month; the other used "quinine capsules vaginally"—pregnant second month.	
1 patient used 7 months and "church made her stop."	
	18

vaginal wall. Next the patient is shown how the diaphragm is correctly placed, and how it is possible for it to be incorrectly placed.

The patient is then given the diaphragm and told to squeeze about one teaspoon (or 1½ inches) of jelly from the tube into the cap, "dome down," and to spread a small amount of the jelly around the edge of the diaphragm.

The diaphragm is compressed and inserted, pushed down as far as possible until the farther end slips into position in the space behind and below the cervix, and then the upper or top edge is pushed behind the pubic bone to hold the diaphragm in place.

After the diaphragm has been put into place the patient is taught to check, with her finger, feeling the cervix through the diaphragm. Coitus may take place immediately or within six hours. If coitus should take place more than six hours later, or is repeated, half an applicator of jelly is inserted well into the vagina with a downward motion. The diaphragm is not to be removed for at least six hours following coitus and may remain longer. To remove the diaphragm, the patient inserts the index finger over the top of the rim of the diaphragm and rotates the hand, withdrawing the diaphragm with a pulling or "flipping" motion. Douching is not necessary and may be omitted if desired. The patient is instructed to wash the diaphragm with toilet soap and warm water following use, and to inspect it for holes. When dry, it should be powdered with corn starch or pure talcum powder.

We do not now uniformly instruct our patients to add an application of jelly following insertion of the diaphragm, although at one time we did advise this technique.

Almost all patients visited the clinic at from two and one-half to three and one-half month intervals. The remaining patients were contacted on an average of every three months by phone, mail or home call. Exceptional cooperation of those patients participating was noted by surveyors.

RESULTS

During the study, 18 pregnancies occurred. Of these, five were noted very shortly after the method was prescribed and it is possible the patients were pregnant before the prescription, although no diagnosis of this was definitely established on the first visit. Therefore they are included in the data according to the usual statistical procedure. As we and others have emphasized in previous reports,[1,3,5] distinguishing between patient-failure and method-failure is extremely difficult. Hence we followed the accepted practice of grouping all failures together. In this connection it is argued by those advocating this grouping that even in cases where patients may admit failure to use a specific method upon occasion during a cycle, it would be erroneous to assume that this was the occasion when conception occurred.

The details of all pregnancies are given in Table 3.

921 Westwood Boulevard, Los Angeles 24 (Olson).

REFERENCES

1. Behne, D., et al.: Clinical effectiveness of a new vaginal contraceptive cream; a preliminary report, W. J. Surg., 64:152, 1956.

2. Berberian, D. A., Coulston, F., and Slighter, R. G.: A New Antiseptic Agent. In press.

3. Tyler, E. T., and Olson, H. J.: Fertility promoting and inhibiting effects of new steroid hormonal substances, J.A.M.A., 169:1843-54, April 18, 1959.

4. Warner, M. P.: Tolerance studies with a new contraceptive gel. Submitted for publication.

5. Wolf, L., Olson, H. J., and Tyler, E. T.: Observations on the clinical use of cream-alone and gel-alone methods of contraception, Obstet. and Gynecol., 10:316, 1957.